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| EXAMINER | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/580,447 | GREENHALGH ET AL. | |
| | Examiner | Art Unit | |
| | Sheridan R. MacAuley | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/28/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-18 are pending and examined on the merits in this office action.

### *Claim Objections*

1. Claim 13 is objected to because of the following informalities. It is recommended that the claims be amended as follows: The term "3-hydroxpropionic" should be changed to "3-hydroxypropionic". Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The term "substantially no removal" in claim 1 is a relative term that renders the claim indefinite. The term "substantially no removal" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, "substantially no removal" could mean that zero, two, or three components of the monomer have been removed.

5. In claim 1, it is also unclear what applicant intends to claim that there be "substantially no removal" of the cellular material and/or components of the fermentation

broth from. The phrase could mean that the molecule of the monomer is not chemically altered in a substantial way, that the cellular material and/or components of the fermentation broth are not physically separated in a substantial way from the solution of monomers, or some other alternative.

6. Claims 2-18 are indefinite insofar as they depend from claim 1.

7. Also, claim 2 recites the limitation "the cellular material and optionally components of a fermentation" in the sixth line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1, from which claim 2 depends, recites "cellular material and/or components of a fermentation broth".

8. In claim 14, it is also unclear which steps in the method are optional and which steps are required by the claims. In the fourth line of the claim, applicant recites a step of "optionally introducing other monomers..." followed by "subjecting the ethylenically unsaturated monomer...". It is unclear whether the step of "subjecting the ethylenically unsaturated monomer..." is required or optional in the claim. It is further unclear whether the step of "forming the polymer inside the vessel", as recited in the last line of the claim, is required or optional. It is recommended that each method step be separated by a semicolon and/or line break to clearly delineate each step.

9. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat.

App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 16 recites the broad recitation *Rhodococcus* genus, and the claim also recites *Rhodococcus rhodochrous*, which is the narrower statement of the range/limitation.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 13 recites the process according to claim 2 in which the substrate is selected from the group consisting of lactic acid, 3-hydroypropionic acid, and glycerol. Claim 2 recites the process according to claim 1 wherein the ethylenically unsaturated monomer is prepared by providing a substrate that can be converted into an ethylenically unsaturated monomer, contacting the substrate with a biocatalyst which

comprises a microorganism or cellular material and thereby converting the substrate into the ethylenically unsaturated monomer containing the cellular material and optionally components of a fermentation and that this process is carried out inside or outside of an the cell and where it is carried out inside the cell and where it is carried out inside the cell it optionally forms part of the metabolic pathway of the microorganism. Claim 1 recites a process for preparing a polymer of an ethylenically unsaturated monomer, in which the monomer is obtainable from a biocatalysed reaction or fermentation process, and wherein the monomer contains cellular material and/or components of a fermentation process; forming the polymer by polymerizing the ethylenically unsaturated monomer or monomer mixture comprising the ethylenically unsaturated monomer, wherein there is substantially no removal of the cellular material and/or components of the fermentation broth from the ethylenically unsaturated monomer.

12. In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be

considered. In the instant case, those factors deemed most relevant are the amount of direction and guidance presented, the presence or absence of working examples, and the state of the prior art.

13. The disclosure is not enabling for the production of a polymer from an ethylenically unsaturated monomer that has been produced by a biocatalysed reaction from lactic acid, 3-hydroxypropionic acid or glycerol because it does not present enough direction an guidance for one skilled in the art to use the invention with a reasonable expectation of success without undue experimentation. The disclosure does not provide any guidance or working examples to direct one to perform the method for the production of a polymer from an ethylenically unsaturated monomer that has been produced by a biocatalysed reaction from lactic acid, 3-hydroxypropionic acid or glycerol. The working examples disclosed in the instant application are directed to the polymerization of fermentation broths using monomers that have not been prepared by a biocatalysed reaction from lactic acid, 3-hydroxypropionic acid or glycerol. Further, the state of the prior art indicates that, at the time of application, the production of acrylic acid by biocatalysed reactions from lactic acid, 3-hydroxypropionic acid or glycerol at concentrations that are suitable for polymerization had not been achieved. Straathof (App. Microbiol. Biotechnol. 2005, 67:727-734) teaches that the development of metabolic pathways for the production of an ethylenically unsaturated monomer (acrylic acid) is still highly speculative, and that the production of acrylic acid from a fermentation process using *Clostridium propionicum* by providing lactate to the organism (note that lactic acid in solution and lactate would be indistinguishable) was

unsuccessful to produce a high yield of acrylic acid (abstract, p. 729, par. 2, fig. 2). Given these facts, one skilled in the art would be unable to predict whether a method for the production of a polymer using an ethylenically unsaturated monomer that has been produced by a biocatalysed reaction from lactic acid, 3-hydroxypropionic acid or glycerol could be performed with a reasonable expectation of success.

14. Therefore, the disclosure of the instant application does not enable one skilled in the art to use the invention as claimed.

15. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

16. The invention appears to employ a specific strain of bacteria to obtain a specific product. The written description of that strain and the method of isolating is insufficiently reproducible. Therefore, a deposit for patent purposes is required. The specification discloses at page 11 that NCIMB 41164 was deposited at the National Collection of Industrial and Marine Bacteria under Budapest Treaty conditions on March 5, 2003.

17. For compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that **all restrictions on the availability to the public of the material so**

**deposited will be irrevocably removed upon the granting of a patent**. See MPEP 2403.

18. Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

### *Claim Rejections - 35 USC § 102*

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 1-7, 10 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Watanabe (US Pat. 4,343,900). Claim 1 recites a process for preparing a polymer of an ethylenically unsaturated monomer, in which the monomer is obtainable from a biocatalysed reaction or fermentation process, and wherein the monomer contains cellular material and/or components of a fermentation process; forming the polymer by polymerizing the ethylenically unsaturated monomer or monomer mixture comprising the ethylenically unsaturated monomer, wherein there is substantially no removal of the cellular material and/or components of the fermentation broth from the ethylenically unsaturated monomer. Claim 2 recites the process according to claim 1 wherein the ethylenically unsaturated monomer is prepared by providing a substrate that can be

converted into an ethylenically unsaturated monomer, contacting the substrate with a biocatalyst which comprises a microorganism or cellular material and thereby converting the substrate into the ethylenically unsaturated monomer containing the cellular material and optionally components of a fermentation and that this process is carried out inside or outside of an the cell and where it is carried out inside the cell and where it is carried out inside the cell it optionally forms part of the metabolic pathway of the microorganism. Claim 3 recites the process according to claim 2 in which the biocatalyst comprises an microorganism and wherein the process is carried out inside the cell and forms part of a metabolic process of the microorganism. Claim 4 recites the process according to claim 1 in which the cellular material comprises whole cells. Claim 5 recites the process according to claim 1 in which the cellular material comprises fractured cellular material. Claim 6 recites the process according to claim 5 in which the fractured cellular material is selected from the group consisting of cell wall material, cell membrane material, cell nucleus material, cytoplasm and proteins. Claim 7 recites the process according to claim 1 in which the components of the fermentation broth are selected from the group consisting of sugars, polysaccharides, proteins, peptides, amino acids, nitrogen sources, inorganic salts (including metal salts), vitamins, growth regulators, enzyme inducers and complex fermentation medium components. Claim 10 recites the process according to claim 2 in which the biocatalyst comprises a nitrile hydratase enzyme. Claim 18 recites a composition comprising a polymer of an ethylenically unsaturated monomer and further comprising cellular material and/or

components of a fermentation broth, wherein the composition is obtainable by a process according to claim 1.

21. Watanabe teaches a process for preparing a polymer of an ethylenically unsaturated monomer, wherein the monomer is obtainable from a biocatalysed reaction (using a microorganism), and wherein the monomer contains components of the fermentation broth (the acrylonitrile), and forming a polymer by polymerizing the ethylenically unsaturated monomer or monomer mixture, wherein there is substantially no removal of the cellular material or the components of the fermentation broth from the monomer (abstract, col. 4, line 44-col. 5, line 31). In the process of Watanabe, a substrate is provided (acrylonitrile) which is converted to the ethylenically unsaturated monomer (acrylamide) by contacting the substrate with the biocatalyst (cells or enzyme; abstract, col. 4, line 44-col. 5, line 31). The process of Watanabe uses whole cells and the biocatalyst is part of a metabolic process that occurs inside of the cells (col. 2, lines 11-15). Watanabe teach that the medium may comprise fractured cellular material, such as proteins (enzymes; col. 2, lines 15-18). The components of the fermentation broth of Watanabe include sugars and other complex fermentation medium components (col. 4, lines 44-50). Watanabe teaches that the organism has nitrilastic activity that converts acrylonitrile to acrylamide, i.e. the organism contains a nitrile hydratase (col. 2, lines 43-50). Watanabe teaches a composition comprising a polymer of ethylenically unsaturated monomer and components of fermentation broth (col. 5, lines 23-33).

Therefore, Watanabe anticipates all of the limitations of the cited claims.

***Claim Rejections - 35 USC § 102/103***

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 1-9, 11, 12, 14-16 and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Armitage et al. (WO97/06248), when taken in view of Seki et al. (US Pat. 5,352,828). Claim 1 recites a process for preparing a polymer of an ethylenically unsaturated monomer, in which the monomer is obtainable from a biocatalysed reaction or fermentation process, and wherein the monomer contains cellular material and/or components of a fermentation process; forming the polymer by polymerizing the ethylenically unsaturated monomer or monomer mixture comprising the ethylenically unsaturated monomer, wherein there is substantially no removal of the cellular material and/or components of the fermentation broth from the ethylenically unsaturated monomer. Claim 2 recites the process according to claim 1 wherein the ethylenically unsaturated monomer is prepared by providing a substrate that can be converted into an ethylenically unsaturated monomer, contacting the substrate with a biocatalyst which comprises a microorganism or cellular material and thereby converting the substrate into the ethylenically unsaturated monomer containing the cellular material and optionally components of a fermentation and that this process is carried out inside or outside of an the cell and where it is carried out inside the cell and where it is carried out inside the cell it optionally forms part of the metabolic pathway of the microorganism. Claim 3

recites the process according to claim 2 in which the biocatalyst comprises an microorganism and wherein the process is carried out inside the cell and forms part of a metabolic process of the microorganism. Claim 4 recites the process according to claim 1 in which the cellular material comprises whole cells. Claim 5 recites the process according to claim 1 in which the cellular material comprises fractured cellular material. Claim 6 recites the process according to claim 5 in which the fractured cellular material is selected from the group consisting of cell wall material, cell membrane material, cell nucleus material, cytoplasm and proteins. Claim 7 recites the process according to claim 1 in which the components of the fermentation broth are selected from the group consisting of sugars, polysaccharides, proteins, peptides, amino acids, nitrogen sources, inorganic salts (including metal salts), vitamins, growth regulators, enzyme inducers and complex fermentation medium components. Claim 8 recites the process according to claim 1 in which the ethylenically unsaturated monomer is methacrylamide monomer. Claim 9 recites the process according to claim 2 in which the substrate is methacrylonitrile. Claim 11 recites the process according to claim 1 in which the polymer is a homopolymer or copolymer of methacrylamide. Claim 12 recites the process according to claim 1 in which the ethylenically unsaturated monomer is selected from the group consisting of itaconic acid (or salts thereof), maleic acid (or salts thereof) and methacrylic acid or salts and derivatives thereof. Claim 14 recites the process according to claim 2 in which the substrate is introduced into a vessel and contacted with a biocatalyst and wherein the substrate is converted into the ethylenically unsaturated monomer, optionally introduction other monomers into the vessel to form a

monomer mixture, subjecting the ethylenically unsaturated monomer or monomer mixture to polymerization conditions, optionally by introducing initiators into the vessel, and thereby forming the polymer inside the vessel. Claim 15 recites a process according to claim 14 in which the biocatalyst is produced inside the vessel. Claim 16 recites a process according to claim 2 in which the biocatalyst comprises microorganisms of the *Rhodoccocus* genus, preferably species *Rhodococcus rhrodochronus*. Claim 18 recites a composition comprising a polymer of an ethylenically unsaturated monomer and further comprising cellular material and/or components of a fermentation broth, wherein the composition is obtainable by a process according to claim 1.

24. Armitage teaches a process for preparing a polymer (a homopolymer or copolymer of methacrylamide) of an ethylenically unsaturated monomer wherein the monomer is obtainable from a fermentation process, and forming the polymer by polymerizing the ethylenically unsaturated monomer (p. 13, lines 23-31, p. 15, lines 14-35). Armitage teaches that the monomer may be prepared by providing a substrate, such as methacrylonitrile, that can be converted into the monomer, contacting the substrate with a biocatalyst, such as a microorganism or cellular material, and converting the substrate into the monomer (p. 15, lines 14-35). Armitage teaches that the biocatalyst can comprise a microorganism (p. 14, lines 28-30, p. 15, lines 14-30). The metabolic process would inherently be carried out inside of the cell. Armitage teaches that the cellular material can comprise whole cells or fractured cells, and that the fractured cellular material can comprise proteins (i.e. enzymes; p. 14, lines 28-30, p.

15, lines 14-30). Armitage teaches that the fermentation broth can comprise components such as nitrogen and inorganic salts (p. 7, lines 23-35). Armitage et al. teaches a process wherein the substrate is introduced into a vessel and contacted with a biocatalyst, which may have been grown in the vessel, wherein the substrate is converted into the ethylenically unsaturated monomer (p. 15, lines 14-35).

25. Armitage does not teach that the polymer is formed in the vessel comprising the ethylenically unsaturated monomer wherein the unsaturated monomer comprises cellular material and/or components of the fermentation broth.

26. Seki teaches that, under most conditions, polymerization of a solution of acrylamide, a ethylenically unsaturated monomer, will occur (col. 2, lines 13-19).

27. At the time of the invention, a process of preparing a polymer comprising nearly all of the claimed elements was known, as taught by Armitage. It was further known that solutions of polymers are likely to polymerize if they are not stabilized. Since the method of Armitage does not explicitly teach stabilizing the fermentation broth against polymerization, it is either inherent to the teachings of Armitage, or it would occur during routine optimization and experimentation, that polymerization of the fermentation broth would occur. One of ordinary skill in the art would have a reasonable expectation of success in polymerizing the fermentation broth taught by Armitage because polymerization of acrylamide solutions is known to occur in such solutions spontaneously, as taught by Seki. Therefore, Armitage anticipates the cited claims, or, in the alternative, it would have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

***Claim Rejections - 35 USC § 103***

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

29. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

30. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

31. Claims 1-12, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe (US Pat. 4,343,900) in view of Armitage et al. (WO97/06248). Claim 1 recites a process for preparing a polymer of an ethylenically unsaturated monomer, in which the monomer is obtainable from a biocatalysed reaction or fermentation process, and wherein the monomer contains cellular material and/or components of a fermentation process; forming the polymer by polymerizing the ethylenically unsaturated monomer or monomer mixture comprising the ethylenically unsaturated monomer, wherein there is substantially no removal of the cellular material and/or components of the fermentation broth from the ethylenically unsaturated monomer. Claim 2 recites the process according to claim 1 wherein the ethylenically unsaturated monomer is prepared by providing a substrate that can be converted into an ethylenically unsaturated monomer, contacting the substrate with a biocatalyst which comprises a microorganism or cellular material and thereby converting the substrate into the ethylenically unsaturated monomer containing the cellular material and optionally components of a fermentation and that this process is carried out inside or outside of an the cell and where it is carried out inside the cell and where it is carried out inside the cell it optionally forms part of the metabolic pathway of the microorganism. Claim 3 recites the process according to claim 2 in which the biocatalyst comprises an microorganism and wherein the process is carried out inside the cell and forms part of a metabolic process of the microorganism. Claim 4 recites the process according to claim 1 in which the cellular material comprises whole cells. Claim 5 recites the process according to claim 1 in which the cellular material comprises fractured cellular material.

Claim 6 recites the process according to claim 5 in which the fractured cellular material is selected from the group consisting of cell wall material, cell membrane material, cell nucleus material, cytoplasm and proteins. Claim 7 recites the process according to claim 1 in which the components of the fermentation broth are selected from the group consisting of sugars, polysaccharides, proteins, peptides, amino acids, nitrogen sources, inorganic salts (including metal salts), vitamins, growth regulators, enzyme inducers and complex fermentation medium components. Claim 8 recites the process according to claim 1 in which the ethylenically unsaturated monomer is methacrylamide monomer. Claim 9 recites the process according to claim 2 in which the substrate is methacrylonitrile. Claim 10 recites the process according to claim 2 in which the biocatalyst comprises a nitrile hydratase enzyme. Claim 11 recites the process according to claim 1 in which the polymer is a homopolymer or copolymer of methacrylamide. Claim 12 recites the process according to claim 1 in which the ethylenically unsaturated monomer is selected from the group consisting of itaconic acid (or salts thereof), maleic acid (or salts thereof) and methacrylic acid or salts and derivatives thereof. Claim 16 recites a process according to claim 2 in which the biocatalyst comprises microorganisms of the *Rhodoccocus* genus, preferably species *Rhodococcus rhrodochronus*. Claim 18 recites a composition comprising a polymer of an ethylenically unsaturated monomer and further comprising cellular material and/or components of a fermentation broth, wherein the composition is obtainable by a process according to claim 1.

32. Watanabe teaches a process for preparing a polymer of an ethylenically unsaturated monomer, wherein the monomer is obtainable from a biocatalysed reaction (using a microorganism), and wherein the monomer contains components of the fermentation broth (the acrylonitrile), and forming a polymer by polymerizing the ethylenically unsaturated monomer or monomer mixture, wherein there is substantially no removal of the cellular material or the components of the fermentation broth from the monomer (abstract, col. 4, line 44-col. 5, line 31). In the process of Watanabe, a substrate is provided (acrylonitrile) which is converted to the ethylenically unsaturated monomer (acrylamide) by contacting the substrate with the biocatalyst (cells or enzyme; abstract, col. 4, line 44-col. 5, line 31). The process of Watanabe uses whole cells and the biocatalyst is part of a metabolic process that occurs inside of the cells (col. 2, lines 11-15). Watanabe teach that the medium may comprise fractured cellular material, such as proteins (enzymes; col. 2, lines 15-18). The components of the fermentation broth of Watanabe include sugars and other complex fermentation medium components (col. 4, lines 44-50). Watanabe teaches that the organism has nitrilastic activity that converts acrylonitrile to acrylamide, i.e. the organism contains a nitrile hydratase (col. 2, lines 43-50). Watanabe teaches a composition comprising a polymer of ethylenically unsaturated monomer and components of fermentation broth (col. 5, lines 23-33).

33. Watanabe does not teach that the substrate is methacrylonitrile and the ethylenically unsaturated monomer is methacrylamide monomer, or methacrylic acid or a derivative thereof. Watanabe does not teach that the polymer is a homopolymer or

colpolymer of methacrylamide. Watanabe does not teach that the biocatalyst comprises microorganisms of the *Rhodococcus* genus, specifically *Rhodococcus rhodochrous*.

34. Armitage teaches a process for preparing an ethylenically unsaturated monomer wherein the monomer is obtainable from a biocatalysed reaction or fermentation process using a substrate (methacrylonitrile) that can be converted into the ethylenically unsaturated monomer (p. 6, lines 1-4, p. 15, lines 14-35). Armitage teaches that a polymer (a homopolymer or copolymer) can be formed by polymerizing the ethylenically unsaturated monomer (p. 13, lines 23-31, p. 15, lines 14-35). Armitage teaches that the biocatalyst can comprise microorganisms of the *Rhodococcus* genus, specifically *Rhodococcus rhodochrous* (p. 8, lines 31-34).

35. At the time of the invention, a process for the preparation of a polymer of an ethylenically unsaturated monomer in which the monomer is obtainable by a biocatalyzed reaction or fermentation process was known in the art, as taught by Watanabe. It was further known in the art that microorganisms of the *Rhodococcus* genus could be used as biocatalysts for the production of ethylenically unsaturated monomers from substrates such as methacrylonitrile, as taught by Armitage. Although Armitage does not disclose the production of methacrylamide from methacrylonitrile, it is taught by Watanabe that acrylonitrile can be converted to acrylamide using the disclosed enzyme, it would therefore be expected that the product of methacrylonitrile would be methacrylamide. Armitage also teaches that homopolymers and copolymers of the ethylenically unsaturated can be formed by polymerization. One of ordinary skill in the art would have been motivated to combine these teachings because the

desirability for conversion of methacrylonitrile into an ethylenically unsaturated monomer was known at the time of the invention, as taught by Armitage, and the process of Watanabe was known to be advantageous (Armitage, col. 2, lines 28-42). One skilled in the art would have a reasonable expectation of success in carrying out the invention because processes for biocatalytically converting acrylonitriles to acrylamides were known to be successful at the time of the invention. One would also expect success in using a *Rhodococcus* species in the method of Watanabe because Watanabe teaches that any microorganism having nitrilastic activity would be suitable for use with the method. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

36. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

## ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

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SRM

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